

IDEAL 2017 Conference Program Draft
Research, Regulation, and Reimbursement in Surgery and Technologies
May 4-5, 2017, New York Academy of Medicine, New York City
1216 5th Avenue, New York, NY 10029

Thursday, May 4th		
7:30 AM: REGISTRATION OPEN		
8:30 AM - 12:30 PM		
Training Courses and Symposia		
Educational workshop: Critical appraisal using IDEAL	IDEAL for devices: regulation and innovation Robotic surgery symposium in context	
<p>Speakers: <i>Peter McCulloch, Oxford</i> <i>Joshua Feinberg, Oxford</i> <i>Chris Pennell, Maimonides</i> <i>Joel Horovitz, Maimonides</i></p> <p>1. What is IDEAL? How it came about and what it is useful for.</p> <p>2. Using IDEAL: Explanation about (a) how to use it to understand the literature (b) how to use it to design research. Interactive discussions with examples for audience to try out (small group discussion to come up with a study design and study conduct plan, focusing on stage 1-3 of IDEAL).</p> <p>3. Disseminating IDEAL: How to present IDEAL studies to journals, funders, and others.</p>	<p><u>Regulation of devices</u> (8:30-10:30 AM)</p> <p>Facilitators: <i>Art Sedrakyan, Weill Cornell</i> <i>Murray Sheldon, FDA</i></p> <p>Speakers: <i>Binita Ashar, FDA</i> <i>Danica Marinac-Dabic, FDA</i> <i>Bruce Campbell, MHRA, UK</i> <i>Iftekhar Kalsekar, Johnson & Johnson</i> <i>Nobuhiro Handa, PMDA, Japan</i></p> <p>The speakers will discuss device regulation in USA, Europe and Japan and focus on recent developments.</p> <p>Important focus will be the lifecycle approach to device evaluation and current frameworks: reflections on IDEAL framework for devices and future advancement needs.</p>	<p><u>Robotic symposium</u> (10:30 AM-12:30 PM)</p> <p>Moderators: <i>Jeffrey Levy, ISE, Drexel</i> <i>Martin Martino, ISE, Lehigh Valley</i> <i>Art Sedrakyan, WCM</i></p> <p>10:30 – 11:55 am Surgical Specialties in Robotic Surgery: Different Stages of IDEAL and Practical Applications</p> <p><i>Urology and OBGYN (Stage 4)</i> <i>Colon and Rectal (Stage 2B)</i> <i>Cardio-Thoracic (Stage 1)</i></p> <ul style="list-style-type: none"> • Binita Ashar, FDA • Vip Patel, Global Robotics Institute • Jim Hu, WCM (Stage 4) • Martin Martino, LVHN • Jason Wright, Columbia • Roberto Bergamaschi, Stony Brook • Sloane Guy, WCM • Jeff Port, WCM • Jaime Wong, Intuitive Surgical <p>11:55 am to 12:30 pm Registry of the Future: Technology Enhancements for “Next Generation” Registries</p> <ul style="list-style-type: none"> • Chaitanya Dahagam, IBM Watson • Derek Streat, C-SATS
12:30 – 1:00 PM: Lunch served		
1:00 PM: Welcome and Opening Remarks, Recognitions, Goals for the Day, <i>Art Sedrakyan, Weill Cornell</i>		
1:10 PM: Patient and Policy Perspective		
1:20 – 3:00 PM: Plenary Session 1 - IDEAL Surgical Innovation/Evaluation: current developments <i>Moderator: Binita Ashar, FDA</i>		
<p>1:20-1:40 IDEAL: IDEAL Template and specific opportunities <i>Peter McCulloch, Oxford</i></p> <p>1:20-2:00 Introduction to IDEAL-D <i>Art Sedrakyan, Weill Cornell Medical College</i></p> <p>2:00-2:20 IDEAL and Innovation at the FDA <i>Murray Sheldon, FDA</i></p>		

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2:20-2:40 IDEAL is continuously improving work in progress
Jane Blazeby, University of Bristol

2:40-3:00 Moderator led discussion and Q&A

3:00 – 5:30 PM: Parallel Tracks: Message from Peter McCulloch, Oxford University
 Clinical think-tanks and abstract presentations. Panel discussion using case studies and reflection on IDEAL and typically adopted approaches. Technology assessments (e.g. trials) nested within registries.

IDEAL Urology <i>Room TBD</i>	IDEAL CT/Vascular Surgery <i>Room TBD</i>	IDEAL Abdominal/Ob-Gyn Surgery <i>Room TBD</i>	IDEAL Orthopedic Surgery <i>Room TBD</i>
<p>Faculty:</p> <ul style="list-style-type: none"> • Vipul Patel, Global Robotics • Binita Ashar, FDA • Peter Schlegel, WCM • Art Sedrakyan, WCM • Mani Menon, Vattikuti Institute (TBC) • Jim Hu, WCM • Charles Viviano, FDA <p>Discussion:</p> <ol style="list-style-type: none"> 1. Robotic comparative effectiveness trial for prostatectomy (Lead: Vipul Patel) 2. Developing HIFU evidence and registry (Lead: Jim Hu) <p>Oral presentation of submitted abstracts</p>	<p>Faculty:</p> <ul style="list-style-type: none"> • Murray Sheldon, FDA • Grace Wang, University of Pennsylvania • Phil Goodney, Dartmouth • Bruce Campbell, MHRA, UK • Greg Ribakove, Maimonides • Darren Schneider, WCM • Pablo Morales, FDA • John Laschinger, FDA • Robert Rhee, Maimonides • Paul Saunders, Maimonides • Jon Boyle, Cambridge • Arash Salemi, WCM • Ajay Kirtane, Columbia <p>Discussion:</p> <ol style="list-style-type: none"> 1. TAVR (Lead: John Laschinger) 2. ECMO (Lead: Paul Saunders) 3. TEVAR (Lead: Grace Wang) <p>Oral presentation of submitted abstracts</p>	<p>Faculty:</p> <ul style="list-style-type: none"> • Cynthia Long, FDA • Mitchell Roslin, Lenox Hill • Peter McCulloch, Oxford University • Jeffrey Milsom, WCM • Martin Martino, LVHN • Joel Horovitz, Maimonides • Roberto Bergamaschi, Stony Brook • Xin Sun, Sichuan University • Jason Wright, Columbia • Lewis Teperman, Northwell • Takeshi Sano, Cancer Institute Hospital, Tokyo • Jane Blazeby, University of Bristol <p>Discussion:</p> <ol style="list-style-type: none"> 1. Bariatric surgery/devices (Lead: Mitchell Roslin) 2. Endoluminal surgery (Lead: Jeffrey Milsom) 3. Robotic OBGYN example (Lead: Jason Wright) <p>Oral presentation of submitted abstracts</p>	<p>Faculty:</p> <ul style="list-style-type: none"> • Andrew Carr, Oxford University • Steven Graves, Australian National Joint Replacement Registry • Liz Paxton, Kaiser Permanente registries • Steering Committee leads: American Joint Replacement Registries • Jeff Dunkel, Titan Spine • David Beard, Oxford • Ron Navarro, Kaiser Permanente <p>Discussion:</p> <ol style="list-style-type: none"> 1. Ceramic hip devices (modular hips: Steven Graves) 2. Bioactive implant first in man (lead: Andrew Carr) 3. Innovative spine devices (lead: Jeff Dunkel) <p>Oral presentation of submitted abstracts</p>

5:30 – 5:45 PM: Summary of the day & agenda for next day
Organizers

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Friday, May 5th		
7:30 AM: REGISTRATION OPEN		
8:00 – 9:00 AM: Summary from Day 1 Clinical Think-Tanks <i>IDEAL presenters</i>		
9:00 – 10:15 AM: Plenary Session 2 - IDEAL Stakeholder Engagement in Education <i>Moderators: Peter McCulloch, Oxford and Art Sedrakyan, Weill Cornell</i>		
<p><u>Education perspective & current surgical research training</u> <i>Ajit Sachdeva, American College of Surgeons</i> Commentary: <i>Binita Ashar, FDA</i></p> <p>UK perspective: NICE, the MHRA and IDEAL <i>Bruce Campbell, MHRA</i> Commentary: <i>Kazuhiro Sase, PMDA, Japan</i></p> <p>Industry exposure to IDEAL: education and outreach <i>Jesse Berlin, Johnson & Johnson</i> Commentary: <i>Theodore Lystig, Medtronic</i></p>		
10:15 – 10:30 AM: Coffee Break		
10:30 – 11:00 AM: Publishing IDEAL – A Conversation with Journal Editors		
<p><i>Moderator: Jose Merino, BMJ</i></p> <p><u>Panel:</u> <i>Riaz Agha, International Journal of Surgery</i> <i>Elizabeth Loder, BMJ</i></p>		
11:00 AM – 12:15 PM: Plenary Session 3 – Health Technology Assessment		
<p>Health technology assessment and IDEAL</p> <table style="width: 100%; border: none;"> <tr> <td style="vertical-align: top; width: 50%;"> <p><u>Moderator:</u> <i>Sean Tunis, CMTF</i></p> <p><u>Panel:</u> <i>Murray Sheldon, FDA</i> <i>Tammy Clifford, CADTH</i></p> </td> <td style="vertical-align: top; width: 50%;"> <p><u>Panel (con't):</u> <i>Suzanne Belinson, Blue Cross Blue Shield</i> <i>Bruce Gingles, ISPOR, Cook Medical</i> <i>Bruce Campbell, MHRA</i> <i>Louis Jacques, ADVI</i> <i>Perry Bridger, Edwards Lifesciences</i></p> </td> </tr> </table>	<p><u>Moderator:</u> <i>Sean Tunis, CMTF</i></p> <p><u>Panel:</u> <i>Murray Sheldon, FDA</i> <i>Tammy Clifford, CADTH</i></p>	<p><u>Panel (con't):</u> <i>Suzanne Belinson, Blue Cross Blue Shield</i> <i>Bruce Gingles, ISPOR, Cook Medical</i> <i>Bruce Campbell, MHRA</i> <i>Louis Jacques, ADVI</i> <i>Perry Bridger, Edwards Lifesciences</i></p>
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12:15 – 1:15 PM: Lunch served, review posters		
1:15 – 3:30 PM: MDEpiNet Session		
1:30 – 2:45: MDEpiNet Update		
<p>The history of MDEpinet as an engine for device life cycle evaluations <i>Danica Marinac-Dabic, FDA</i></p> <p>Creating coordinated registry networks & utilizing routinely available data for device research <i>Art Sedrakyan, Weill Cornell</i></p> <p>More efficient evaluation using registries and Bayesian approaches <i>Marion Campbell, University of Aberdeen</i></p> <p>UDI database interoperability with registries: illustrative example with vascular devices <i>Behnaz Minaei, FDA and Phil Goodney, Dartmouth</i></p> <p>Discussion with audience</p>		

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2:45 – 3:30 PM: Introduction to National Evaluation System for Devices – IDEAL Opportunity

Medical Device Innovation Consortium (MDIC) think-tank with MDEpiNet

Planned efforts and possible IDEAL contribution

Moderator:

Greg Pappas, FDA

Presentation by *Bill Murray, MDIC*

Panel:

Rachael Fleurence, MDIC

Dawn Bardot, MDIC

Cynthia Long, FDA

Myoung Kim, Johnson & Johnson

Danica Marinac-Dabic, FDA

Art Sedrakyan, Weill Cornell

Closing Remarks:

Art Sedrakyan, Weill Cornell

Paper Posters can be viewed during lunch time

Notes:

TBC, To Be Confirmed

TBD, To Be Determined

DRAFT